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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,827	04/23/2001	Andrew J Garman	3764-78	3757

7590 08/27/2002

Nixon & Vanderhye
1100 North Glebe Road 8th Floor
Arlington, VA 22201-4714

EXAMINER

COUNTS, GARY W

ART UNIT PAPER NUMBER

1641

DATE MAILED: 08/27/2002 12



Please find below and/or attached an Office communication concerning this application or proceeding.

Final

DOCKETED

CLT/MATTER # 3764-78
MAIL DATE 8-27-02
DUE DATE Nov. 27, 2002
FINAL DEADLINE Feb 27, 2003
DOCKETED BY per/ms

Office Action Summary

Application No.

09/763,827

Applicant(s)

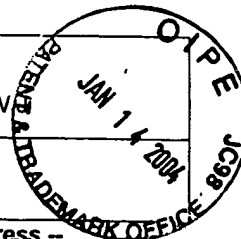
GARMAN, ANDREW

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,8 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the claims

The amendment filed on June 11, 2002 in paper No. 9 is acknowledged and has been entered.

Claim Rejections – 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 6, lines 6-9 in the specification. The applicant discloses the diffusion occurs on either side of the diffusion area. The applicant does not disclose that the diffusion is detected either side of the diffusion region. On page 7, lines 24-27 in the specification. The applicant disclose that the detector monitors the labeled component flowing past a single point. The applicant does not disclose that the diffusion is detected either side of the diffusion region. There is no description in the specification disclosing that the diffusion is detected either side of the diffusion region.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2, 3, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite because it is unclear how the inlet conduit is positioned so that it occupies the whole area of cross section that results in an area which is smaller than the length of the microfabricated conduit as indicated in Figure 4. Further, it is unclear how the liquid is delivered to both sides of the test compound. See also deficiency found in claim 8.

Claim 9, line 1 "diffusion is detected" is vague and indefinite. What diffusion is detected i.e. the diffusion of the test compound, or the ligand, or liquid?

Claim Rejections – 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Yager et al (WO 97/47390).

Yager et al disclose a microdevice comprising (1) a sample stream inlet; (2) an extraction stream inlet; (3) an extraction channel in fluid communication with sample stream inlet and extraction stream inlet for receiving a sample stream from sample stream inlet in adjacent laminar flow with an extraction stream from extraction stream inlet; (4) and two outlets which divide the laminar flow into a by-product stream outlet and a product outlet (page 3, line 17 to page 4, line 8). Yager et al also disclose the

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use of a detector with the device to detect the presence of desired analyte particles (page 19, lines 14-23).

With respect to a diffusion region within the microfabricated conduit which defines an area which is smaller than the length of the microfabricated conduit as recited in the instant claims. Yager et al disclose a diffusion region which is variable (See Figure 2). Yager et al disclose that the sample stream and extraction stream form a laminar sample stream and laminar extraction stream within an extraction channel 7 and form a product stream with exaction channel 7. The product stream is formed after diffusion within the extraction stream. Therefore, Yager et al disclose a diffusion region within the conduit which defines and area which is smaller than the length of the microfabricated conduit.

Claim Rejections – 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yager et al (WO 97/47390) in view of Wu et al (US Patent 6,297,061).

See above for teachings of Yager et al.

Yager et al differ from the instant invention in failing to disclose introducing a liquid and introducing a mixture comprising a test compound, a receptor and a ligand.

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Yager et al also fail to disclose detecting the diffusion of the test compound, or the ligand out of the diffusion region.

Yager et al disclose introducing in one inlet a mixture comprised of antigen, antibody and analyte. An extraction fluid is introduced in another inlet and the two streams join in adjacent laminar flow in joining a channel (col 7, lines 48-64, see also figure 7). This allows for the movement of different layers of fluid and particles next to each other in a channel without any mixing other than diffusion (col 1, lines 42-44) and also allows for simultaneous chemical reaction (col 1, lines 49-50). Yager et al also disclose detecting the diffusion of the test compound, or ligand out of the diffusion region. Yager et al disclose that competitive immunoassays can be incorporated into the method and that at the downstream end of the crossbar (conduit), the residual sample stream and the product stream divide into the two downstream arms of the device and that the product particles can then be detected in the product stream. The detection of the product particles can be performed by using optical, electrical, chemical, electrochemical or calorimetric analysis (col 2, lines 18-58). This allows for simultaneous chemical reaction, which facilitates the elimination of preprocessing of specimens containing particulate constituents, thus reducing the sample size and analytical time required (col 1, lines 49-53).

It would have been obvious to one of ordinary skill in the art to incorporate introducing an extraction fluid and a mixture as taught by Wu et al into the device of Yager et al because Wu et al teaches that this allows for the movement of different

layers of fluid and particles next to each other in a channel without any mixing other than diffusion and also allows for simultaneous chemical reaction.

It would also have been obvious to one of ordinary skill in the art to incorporate detection of immunoassay components as taught by Wu et al into the device of Yager et al because Wu et al shows that this allows for simultaneous chemical reaction, which facilitates the elimination of preprocessing of specimens containing particulate constituents, thus reducing the sample size and analytical time required.

Response to arguments

Applicant argues that Yager et al does not teach the diffusion region within the microfabricated conduit defines an area which is smaller than the length of the microfabricated conduit. This is not found persuasive because Yager et al disclose a diffusion region which is variable (See Figure 2). Yager et al disclose that the sample stream and extraction stream form a laminar sample stream and laminar extraction stream within an extraction channel 7 and form a product stream with exaction channel 7. The product stream is formed after diffusion within the extraction stream. Therefore, Yager et al disclose a diffusion region within the conduit which defines and area which is smaller than the length of the microfabricated conduit.

Applicant argues that Yager et al does not disclose or suggest introducing a liquid and introducing a mixture comprising a test compound and a receptor, or a test compound, a receptor and a legend into a diffusion region defining an area which is smaller than the length of the microfabricated conduit. This is not found persuasive because Yager et al disclose a diffusion region which is variable (See Figure 2). Yager

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et al disclose that the sample stream and extraction stream form a laminar sample stream and laminar extraction stream within an extraction channel 7 and form a product stream with exaction channel 7. The product stream is formed after diffusion within the extraction stream. Therefore, Yager et al disclose a diffusion region within the conduit which defines and area which is smaller than the length of the microfabricated conduit.

Applicant further argues that Wu et al does not disclose or suggest differential diffusion. This is not found persuasive because the recitation of differential diffusion is not recited in the instant claims.

Conclusion

No claims are allowed.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

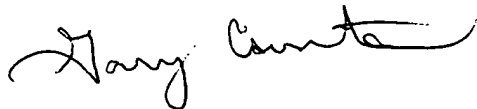
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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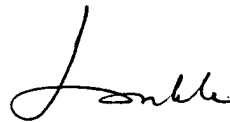
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts
Examiner
Art Unit 1641
August 26, 2002



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

08/26/02

Interview Summary

Application No.

09/763,827

Applicant(s)

GARMAN, ANDREW J

Examiner

Gary W. Counts

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All participants (applicant, applicant's representative, PTO personnel):

(1) Gary W. Counts, Examiner.

(3) _____.

(2) Linda, Secretary.

(4) _____.

Date of Interview: 09 August 2002.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.

If Yes, brief description: _____.

Claim(s) discussed: none.

Identification of prior art discussed: _____.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☐ N/A.


Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Called applicant concerning missing page 6 of Applicant's response filed in paper no. 9. Applicant confirmed that page 6 was the exact as page 17.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☐ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.